Department of Energy
Washington, DC 20585

May 3, 2001

MEMORANDUM FOR DISTRIBUTION

FROM: CAROLYN L. HUNTOON
ACTING ASSISTANT SECRETARY FOR
ENVIRONMENTAL MANAGEMENT

Carolyn L Huntoon

SUBJECT: USE OF STATISTICAL METHODOLOGY (95 PERCENTILE) FOR ENVIRONMENTAL MANAGEMENT DOCUMENTED SAFETY ANALYSES

Until further notice, the proposed alternate approach to accident dose calculation methodology (generally referred to as the "95 percentile methodology") shall not be used for Environmental Management (EM) nuclear facility Documented Safety Analyses under the requirements of 10 CFR 830 Rule Subpart B.

The Office of Environment, Safety and Health (EH) and the Defense Nuclear Facilities Safety Board have clearly expressed significant concerns with the application of this approach (see attached correspondence). The consensus of both organizations is that this methodology does not fall within the Rule "safe harbor" boundaries.

I have directed the Office of Safety, Health and Security to work closely with EH, as well as EM Headquarters line and field organizations, to further evaluate the technical merits and potential acceptability of this methodology.

Please contact Mr. Randal S. Scott, Director, Office of Safety, Health and Security, at (202) 586-0755 or Dr. Maria Gavrilas-Guinn at (202) 586-2232 (maria.gavrilas-guinn@em.doe.gov), for any questions related to this effort.

Attachments

Distribution:
Beverly Cook, Manager, Idaho Operations Office (ID)
Dr. Susan Brechbill, Manager, Ohio Field Office (OH)
Keith Klein, Manager, Richland Operations Office (RL)
Dr. Harry Boston, Manager, Office of River Protection (ORP)
Barbara Mazurowski, Manager, Rocky Flats Field Office (RF)
Greg Rudy, Manager, Savannah River Operations Office (SR)
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Eugene Schmitt, Act. Deputy Assistant Secretary for Policy, Planning, and Budget, EM-10
David Huizenga, Deputy Assistant Secretary for Integration and Disposition, EM-20
James Fiore, Deputy Assistant Secretary for Site Closure, EM-30
Mark Frei, Deputy Assistant Secretary for Project Completion, EM-40
Gerald Boyd, Deputy Assistant Secretary for Science and Technology, EM-50

cc:
R. Black, EH-53
R. Englehart, EH-53
M. Whitaker, S-3.1
L. Wade, EM-23
K. Chaney, EM-31
R. Nace, EM-32
M. Jones, EM-33
J. Lehr, EM-34
S. Robison, EM-41
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United States Government **Department of Energy**

memorandum

DATE: April 18, 2001

REPLY TO
ATTN OF: Office of Nuclear and Facility Safety Policy:REnglehart:301-903-3718

SUBJECT: Proposed 95% Methodology

TO: Maria Gavrillas-Guinn, EM-5

The purpose of this memorandum is to transmit to the Office of Environmental Management (EM) the findings and recommendations to date of the Office of Facility and Nuclear Safety Policy (EH-53) on the proposed use of the so-called 95% statistical methodology in the preparation of Documented Safety Analyses (DSAs) under the requirements of 10 CFR 830 Subpart B.

This methodology was brought to our attention by the DNFSB in a letter from Chairman Conway to the Assistant Secretary of EH dated November 1, 2000. The DNFSB letter expressed concern that a local approval authority could override established DOE standards and guides for facility safety documents. The letter was stimulated by a Safety Analysis Report (SAR) for the Cold Vacuum Drying Facility (CVDF) at Hanford that utilized the methodology. This Office reviewed the CVDF "delta SAR" and the draft Safety Evaluation Report (SER) prepared by Richland Operations (RL). A concern that the CVDF might not be compliant with 10 CFR 830 led to a telephone conference between representatives of EM, RL, the DNFSB, and ourselves. We advised RL that the methodology appeared not to be consistent in approach with DOE-STD-3009, a safe harbor methodology under the Nuclear Safety Management rule, 10 CFR Part 830. RL promised to respond to several questions posed by the DNFSB representatives.

In a December 19, 2000, response to the DNFSB, the EH Assistant Secretary indicated that EH shared the Board's concerns and would take action to revise the DOE Functions, Responsibilities, and Authorities Manual (FRAM) to require EH concurrence on the use of alternate methodologies to the rule safe harbors, would develop guidance on the review and approval of alternate methodologies, and would work with line organizations regarding proposed methodologies. The provision requiring EH concurrence for alternate methodologies is established in the Interim Implementation Guide for Use in Developing Documented Safety Analysis, DOE G 421.X-X.

In later conversations with Savannah River Operations Office (SR) personnel, we found that Westinghouse Safety Management Solutions (WSMS) was developing the methodology and had consulted with RL in its use there. SR (Mosi Dayani) arranged for a workshop conducted by WSMS, to which RL was invited, to present details of the proposed methodology and to further explore these developments. The attached Technical Report contains our assessment of the information presented during the workshop. It shows that the 95% methodology is currently incomplete and inadequate.

We note that, prior to the workshop, the Office of River Protection (ORP) Assistant Manager for Environmental Safety, Health, and Quality issued a memorandum to the Manager of ORP asserting that the so-called 95% statistical methodology "fall(s) within the safe harbor provisions of 10 CFR 830." We recommend that EM clarify the intent and meaning of the March 8, 2001, Johnson to Boston memorandum.

On April 10, 2001, DNFSB Chairman Conway sent a letter to the Secretary of Energy expressing concern that "some DOE offices and some DOE contractors are moving to use this unapproved methodology to revise their authorization basis documents." The letter included an attachment providing the Board's review of the 95% methodology. We fully concur with the Board's assessments, including its conclusion that it does not fall within the rule safe harbors.

In accordance with the proposed FRAM revisions and the commitments made to the DNFSB, this Office advises EM that the proposed methodology has not been sufficiently developed or reviewed to be accepted as an additional safe harbor for the DSA requirements of 10 CFR 830. The attached Technical Report outlines the issues and questions that must be addressed in order for our review to proceed.

Richard L. Black

Richard L. Black, Director
Office of Nuclear and
Facility Safety Policy

Attachment: EH-53 Technical Report and
Summary, Proposed 95%
Statistical Methodology

cc: Mosi Dayani, DOE-SR
Dae Chung, DP-45
Kamiar Jamali, DP-45
Robert Nelson, DOE-RL
Farid Bamdad, DNFSB
Mark Whitaker, S-3.1
Mark Frei, EM-40
Thomas Hull, EM-43

EH-53 TECHNICAL REPORT AND SUMMARY

PROPOSED 95% STATISTICAL METHODOLOGY

This report documents the findings of EH-53 personnel (R. Stark and R. Englehart) relative to the statistical methodology as an alternate methodology to DOE-STD-3009 for the classification of structures, systems, and components (SSCs) as Safety Class in the preparation of Documented Safety Analyses (DSA).

The nuclear safety management rule (10 CFR Part 830) requires a contractor to develop a DSA for Category 1, 2 and 3 hazard nuclear facilities and have it approved by DOE. Table 2 to Appendix A of 10 CFR Part 830 establishes methodologies to develop a DSA that have been approved by DOE (the so-called safe harbors). A contractor may chose to use a different methodology but its use must be pre-approved by DOE. Under the provisions of DOE G 421.X-X and the FRAM, alternate methodologies to those of the 10 CFR Part 830 safe harbors for nuclear facility safety bases will require line management approval, with EH concurrence (or, comment to NNSA).

Westinghouse Safety Management Solutions (WSMS) has proposed to use a so-called 95% statistical methodology in lieu of DOE-STD-3009 which is the established safe harbor for nonreactor nuclear facilities. In light of potential concerns regarding the proposed methodology raised by DOE and DNFSB personnel, a workshop was held at the Savannah River Site (SRS) on March 15, 2001, for a presentation on the methodology and a general discussion on potential issues and concerns.

The workshop was arranged by M. Dayani of the Department of Energy (DOE)-Savannah River Operations Office (DOE-SR) and was attended by about 50 persons, most of them from Westinghouse Savannah River Company, WSMS, and DOE-SR. DOE-Headquarters personnel in attendance were Richard Englehart and Richard Stark of EH, and Maria Gavrillas-Guinn and Raymond Lopiccolo from Office of Environmental Management (EM). DNFSB staff (Bamdad, Burns, and Andrews) were also in attendance. In addition to the presentations made by WSMS on the methodology, a presentation was made on the application of the methodology for the Hanford Tank Farms by Y. Noorani and R. Nelson of ORP and the DOE-Richard Operations Office (RL).

It was asserted that the presentation was made strictly to support the potential application of the methodology at SRS for the selection of Safety Class structures, systems, and components (SSCs). However, we note that the general approach is very similar to that used at RL in the preparation of the DSAs (or, Safety Analysis Reports) for the Hanford Tank Farm and the Cold Vacuum Drying Facility (CVDF). That application stimulated a letter from Chairman Conway of the DNFSB to the Assistant Secretary of EH, Dr. David Michaels, dated November 1, 2000. The DNFSB letter expressed concern that the local approval authority could override DOE standards and guides for facility safety documents. Specifically, Chairman Conway commented:

"This methodology reduces the conservatism in the current DOE recommended approach by using a probabilistic combination of uncertainties or errors in calculating unmitigated consequences."

Unmitigated consequence calculations are done for the purpose of classifying safety systems important to public safety as Safety Class. Dr. Michaels replied to Chairman Conway's letter on December 20, 2000, saying that EH would propose, in a revision to the FRAM, that EH approval would be necessary for deviations from 10 CFR 830 safe harbor methodologies. Dr. Michaels also indicated that EH would work with the line organizations to assess and resolve any deficiencies in the statistical methodology. DOE has made the proposed revision to the FRAM that is consistent with a corresponding discussion of DOE approval in the 10 CFR 830 Implementation Guides. We have previously commented on the CVDF application at the request of RL and have participated in a telephone conference with EM, DNFSB, and RL on this application. Potential concerns with the application of the methodology led to the workshop.

Prior to the workshop a draft paper titled "Statistical Methodology in Safety Analysis," dated March, 2001 was distributed. Presentations and a demonstration were made by WSMS (George Clare and Al Wooten) on the methodology and its application. Briefly the methodology involves:

- assigning statistical distributions to data associated with up to eight multiplicative parameters used in calculating an accident radiation dose,
- performing dose calculations using these distributions to arrive at a probability distribution of dose, and
- selecting a dose result at the 95^{th} percentile level of the distribution as "a reasonably conservative" value for use in comparison with the Evaluation Guideline for Safety Class SSCs.

This is in contrast to the method described in Appendix A to DOE-STD-3009, which specifies the use of reasonably conservative values of each parameter. The draft paper claims that use of the statistical methodology reduces calculated doses by a factor up to 600, depending on the specific circumstances. Although it was not shown during the workshop or in the draft paper, the presenters committed to provide the details of how these reduction factors were obtained. They indicated that the factors would need to be redone based on newer information and with consideration of the questions that were asked during the workshop. The presentations contained much more information than the draft paper contained.

At the conclusion of the workshop, we presented our reaction and recommendation regarding this methodology. The following paragraphs expand upon these. This should not be regarded as a complete list of technical issues that the methodology needs to address; however, they do outline some of the more significant ones resulting from information provided to date.

Inconsistent with approved methodology (3009).

It is quite clear that the methodology is not consistent with that of DOE-STD-3009, especially in the context of the proposed use in classifying Safety Class SSCs. Appendix A to DOE- STD-3009 is quite explicit on the method to be used. It was made explicit in order to achieve uniformity throughout the complex with regard to Safety Class SSCs. The central difference is that STD-3009 specifies "that calculations be based on reasonably conservative estimates of the various input parameters," rather than on statistical distributions of limited data. One of the parameters (leakpath factor) must be set to unity per STD-3009. The proposed methodology would permit use of a statistical distribution of this factor.

Unwarranted extrapolations of limited experimental data.

DOE-STD-3010, which was referenced as being the primary source for accident parameters for this methodology, specifically cautions against using distributions of very limited experimental data. In order to achieve some sort of uniformity and repeatability, a well-defined protocol and criteria needs to be established that would be used to obtain and qualify a statistical distribution for use in the methodology. This protocol and the criteria need to deal with the uncertainties associated with individual data points, confidence levels associated with a set of data, the amount of data needed to define a distribution, etc. There is no indication that the proposed methodology has addressed the issue of uncertain data.

Lack of compatibility of the methodology with the Evaluation Guideline.

The use of the proposed methodology is to compare a calculated accident dose with the Evaluation Guideline for designation of a Safety SSC as Safety Class. The Evaluation Guideline for Safety Class SSCs of 25 rem was selected in the context and understanding of the conservatism inherent in the method of calculating unmitigated accident doses described in DOE-STD-3009. The proposed methodology, it is claimed, would reduce calculated doses by up to a factor of 600. That being the case, the proposed methodology needs to address the issue of whether the EG needs to be adjusted to provide the same level of assurance of safety for the public as would use of DOE-STD-3009 methodology.

Path forward.

It is apparent that the draft paper "Statistical Methodology in Safety Analysis," dated March, 2001 does not include all the development work done to date, and it is also apparent that further work remains to be done to provide complete documentation of the methodology sufficient for review. It has been recommended to Westinghouse that a topical report be developed that would provide the basis for a review for acceptance of this methodology as an additional safe harbor for the 10 CFR 830 nuclear safety basis requirements in a generic sense.

It is possible that the proposed methodology has some useful application in helping to understand the relative importance of various alternative accident mitigation strategies. Its role, in relation to prevention strategies, needs to be described more fully. Also, the limitations on use of the methodology need further development.

At the conclusion of the workshop the presenters developed a list of "needs" that included the development of a side-by-side comparison of the margins in the STD-3009 methodology and the proposed statistical methodology; development of a protocol; characterization of benefits; description of the process as related to hazard analysis, accident analysis, control selection, and TSR development; and a peer review, among others. These needs and the issues discussed in this report need to be addressed in order for this proposed methodology by approved by DOE as an additional safe harbor for the preparation of DSAs to meet the requirements of 10 CFR 830, Subpart B.

EM-5 FOR YOUR INF
CC EM-1,2,3, GUNUKE
HARROD

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

625 Indiana Avenue, NW, Suite 700, Washington, D.C. 20004-2901
(202) 694-7000

April 10, 2001

The Honorable Spencer Abraham
Secretary of Energy
1000 Independence Avenue, SW
Washington, DC 20585-1000

Dear Secretary Abraham:

On November 1, 2000, the Defense Nuclear Facilities Safety Board (Board) wrote to the Assistant Secretary for Environment, Safety and Health (EH) concerning an accident dose calculation methodology ("95 percentile methodology") being advanced for use at the Hanford site that did not follow established Department of Energy (DOE) guidelines. In that letter, the Board acknowledged that "this proposed methodology may prove useful in certain applications" but also noted that "there is a potential for misapplication" and that "the Office of Primary Interest for nuclear safety analysis directives needs to evaluate this methodology, assess its applicability to authorization basis activities, and if appropriate, establish relevant standards and guidelines."

The Assistant Secretary responded on December 19, 2000, stating: "We have reviewed that methodology and we share the Board's concern that it may reduce the conservatism of the methodology described in DOE-STD-3009 to unacceptable levels. We have discussed this matter with individuals at the involved site and are working toward a resolution of the problem." It was the Board's understanding from this letter that use of the methodology to revise authorization basis documents would not be permitted by DOE pending completion of the EH-led review and issuance of guidelines.

Contrary to this understanding, it appears that some DOE offices and some DOE contractors are moving toward the use of this unapproved methodology to revise their authorization basis documents. The Board has identified a number of issues that need to be addressed prior to using such a methodology for identification and classification of safety controls. As summarized in the enclosure to this letter, application of the proposed methodology could lead to a downgrading of safety controls otherwise required by DOE safety orders and standards and by 10 C.F.R. Part 830, *Nuclear Safety Management Rule*. In the Board's view, this should not be permitted to occur until proper review by both DOE and the Board of any proposed guidelines and standards is completed and DOE has revised and re-issued the applicable standards per prescribed processes. See 42 U.S.C. § 2286a(a)(1).

The Board requests that you look into this issue promptly and, pursuant to 42 U.S.C. § 2286b(d), provide a report to the Board within 60 days of receipt of this letter that includes: (1) the merits and applicability of the proposed statistical methodology, (2) if appropriate, DOE's path forward for completing the EH review and issuing the necessary guidelines for application of the statistical methodology, and (3) how DOE intends to ensure that this EH guidance is in place prior to accepting authorization basis documents that incorporate the statistical methodology.

Sincerely,

by HHO FOR

John T. Conway
Chairman

c: The Honorable Carolyn L. Huntoon
Mr. Greg Rudy
Mr. Keith A. Klein
Mr. Steven V. Cary
Mr. Mark B. Whitaker, Jr.

Enclosure

ENCLOSURE

The Board and its staff have reviewed the proposed statistical methodology ("95 percentile methodology") and met with Department of Energy (DOE) and contractor representatives on several occasions. The discussions focused on the details of the technical bases and applicability of the proposed approach to dose calculations and functional classification of safety structures, systems, and components (SSCs). The proposed approach reduces the numerical value of the calculated consequences by reducing the level of conservatism in the corresponding parameters. As a result, the Board has raised the following issues which need to be addressed prior to any application of this methodology to the authorization bases of defense nuclear facilities:

- The statistical approach to accident analysis has been proposed in response to a *perceived* concern that the current bounding methodologies yield excessively conservative dose estimates, thereby requiring facilities to maintain unreasonable and burdensome functionally classified safety SSCs. A convincing case has yet to be made that current safety related controls are either unreasonable or burdensome. Similarly, it has not been demonstrated that a more conscientious application of the current methodologies (e.g., better accident progression models, improved characterization of input data) would not serve to relax potential overconservatism in existing accident analyses.

- A fundamental aspect of the proposed approach to accident analyses is the identification of statistical distributions for the various accident model input parameters (e.g., material at risk, damage ratio, aerosolized release fraction). The paucity of underlying data makes it extremely difficult to identify justifiable parameter distributions, and protocols have yet to be established with regard to how acceptable distributions are to be developed in the absence of adequate supporting data. Furthermore, use of this proposed methodology leads to statistically distributed initial conditions that the contractors may be obligated to maintain under their Technical Safety Requirements for operational safety. An acceptable way of translating a distributed parameter into a practical Technical Safety Requirement has not yet been identified.

- The proposed approach does not seem to be enveloped by the "safe harbor" methodology of the Nuclear Safety Management Rule, 10 C.F.R. Part 830. EH-53, the DOE Office of Primary Interest for the rule, has since concluded the same, and has requested a topical report be submitted for review and approval prior to use of the proposed methodology.

- In a letter to DOE dated July 8, 1999, the Board accepted the current conservative methodology for accident analysis in conjunction with the use of an evaluation guideline of 25 rem for functional classification as a coupled package that, when used together, represent an acceptable approach for the identification and classification of safety controls. In contrast, use of the existing evaluation guideline (25 rem) as the basis for interpreting dose estimates from the proposed statistical methodology is inappropriate, as it would result in the elimination or downgraded functional classification of many safety related controls, thereby reducing the safety margin of a facility or activity.

- Application of the proposed statistical methodology appears skewed toward identification of mitigative controls versus preventive controls. This is due to the fact that the statistical methodology places emphasis on how to minimize the quantitative radiological consequences of an event without first focusing on how the event can be prevented.